

UNITED STATES OF AMERICA
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

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IN RE: NATIONAL PRESCRIPTION

OPIATE LITIGATION

THIS DOCUMENT RELATES TO:

Track Three Cases

Case No.

1:17-MD-2804

Honorable

Dan A. Polster

- - - - -

TRANSCRIPT OF DAUBERT HEARING VIA ZOOM PLATFORM

BEFORE JUDGE DAN A. POLSTER, JUDGE OF

SAID COURT, ON FRIDAY, SEPTEMBER 10TH, 2021,

COMMENCING AT 9:30 O'CLOCK A.M.

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Court Reporter:

GEORGE J. STAUDUHAR
801 W. SUPERIOR AVE.,
SUITE 7-184
CLEVELAND, OHIO 44113
(216) 357-7128

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1 **APPEARANCES:**

2 On behalf of the Plaintiffs:

3 SPANGENBERG SHIBLEY & LIBER
4 BY: PETER H. W , AUSA
5 1001 Lakeside Avenue East, Suite 1700
6 Cleveland, OH 44114

7 On behalf of Defendant CVS:

8 ZUCKERMAN SPAEDER, LLP
9 BY: GRAEME W. BUSH, ESQ.
10 485 Madison Avenue
11 10th Floor
12 New York, New York 10022-5871

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I N D E X

WITNESSES:EXAMINATION

By the Court

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By Mr. Bush

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By the Court

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By Mr. Bush

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By Mr. Weinberger

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P R O C E E D I N G S

THE COURT: All right. This is a Daubert hearing in MDL 2804, the Track Three case that is set to go to trial the end of this month. I requested to ask some questions of Dr. Anna Lembke, who is one of the Plaintiffs' witnesses, and the Defendants had filed a Daubert motion challenging some or all of Dr. Lembke's proposed testimony.

My plan is that I will conduct most of the questioning because I am the one who is going to have to make a decision, and I think I know the questions I have. I have got several areas I am going to cover.

And then, when I complete an area, I will allow some brief questioning by the Plaintiffs and with one counsel for the Plaintiffs and one counsel for the Defendants, and then I will move on to another area.

I have got a hard stop at 11:30, so this is not going to drag on. I want to focus on the areas that are of my concern. So focusing on the screen, do we have Dr. Lembke?

JUDICIAL ASSISTANT: Your Honor, she is in the waiting room. I was just waiting for you to take the bench. I will admit her now. One moment.

THE COURT: Okay. I just want --

JUDICIAL ASSISTANT: Your Honor, Dr. Lembke

1 is now in the meeting with a white background.

2 Dr. Lembke, if you could just say hello?

3 THE COURT: Oh, right in the center. Fine.

4 Thank you, Doctor.

5 And I appreciate your getting up so early.

6 When I had scheduled this, I was not focusing on the fact

7 we might have witnesses on the West Coast. So thank you

8 very much. So I need to swear you in, so if you could

9 raise your right hand, please?

10 DR. ANNA LEMBKE

11 called as a witness by and being first duly sworn,

12 was examined and testified as follows:

13 EXAMINATION BY THE COURT

14 THE COURT: All right. Thank you.

15 BY THE COURT:

16 Q. All right. Starting with a general question,

17 Doctor, in your role as a physician, do you regularly

18 interact with pharmacists? So I would like you to

19 describe how and what those interactions entail and how

20 often you interact with pharmacists.

21 A. Yes. I regularly interact with pharmacists. I

22 interact with pharmacists on multiple times, on most

23 clinic days, which constitute currently about half of the

24 days in my week but through various points in my career

25 constituted every work day, Monday through Friday.

1 On any given day, I will interact with
2 pharmacists typically by phone. Multiple times in a day
3 around the prescription with the advent of the electronic
4 medical records, I also have many interactions, probably
5 on the order of 10 to 20 interactions electronically with
6 pharmacists.

7 Over the past two decades those interactions
8 have qualitatively and quantitatively changed vis-a-vis
9 opioid prescribing, but I can give you an example of an
10 interaction I had with a pharmacist on Tuesday to give
11 you a real-time example of an interaction.

12 Q. That would be helpful. Thank you.

13 A. Okay. So on Tuesday, I got a call from a pharmacist
14 leaving a message on my phone letting me know that she
15 was concerned about an opioid prescription for
16 buprenorphine. Trade name is Suboxone. Under my name,
17 she had received a call from somebody calling in the
18 prescription and giving my DEA number and my name but was
19 obviously a male voice?

20 And so she took the prescription, but then,
21 after hanging up with that person called me and left a
22 message and said "can you just verify this is, indeed, a
23 real and true prescription from you?"

24 So I called her back, and I asked the name
25 of the patient and when it was called in, and I let her

1 know that I had not made that phone call, and that I was
2 concerned, and that I appreciated she had called me about
3 that, and that I thought there was a possibility I
4 thought it was one of my fellows who had used my DEA
5 instead of his DEA, and that she should not dispense
6 until I investigate it further.

7 I touched base with my fellow who is new
8 here to the Clinic and has not yet gotten his DEA and
9 said it was, indeed, him and that he had called it in
10 under my DEA.

11 So I then called her back and said it is
12 okay to dispense. That is a patient of ours. He is
13 switching pharmacies because he is moving. I was aware
14 that he had been moving?

15 But he is a person with severe opioid use
16 disorder, and people can relapse at any point in their
17 trajectory, even though he has been in recovery for
18 several years knew?

19 And then I thanked the pharmacist for doing
20 her due diligence and confirming that it was, indeed, a
21 legitimate prescription. So that is one example of the
22 kinds of interactions I will have with pharmacists.

23 I am having many more of those kind of
24 interactions around opioid dispensing and double checking
25 for red flags around opioid dispensing in the past two to

1 five years than I had prior to that, so it is good to see
2 there is a see-change happening.

3 Q. All right. So your interactions with pharmacists in
4 your practice generally center around particular
5 prescriptions that you prescribed, either you are
6 contacting them or like in the example you just cited,
7 when they received a prescription purportedly from you to
8 double check it?

9 A. Yes.

10 Q. That's the way your interactions -- okay. That's
11 what I thought.

12 Let me follow up on what you just said. You
13 said that there has been a see change in the last two to
14 five years around interactions pertaining to
15 prescriptions for opioids.

16 Will you elaborate on that a little more,
17 please?

18 A. Yes. So in our clinic, we made checking the PDMP
19 prior to checking a controlled substance mandatory around
20 2013, and once we started doing that, we saw many
21 instances of, for example, doctor shopping, patients
22 going around to multiple prescribers to get the same or a
23 similar prescription.

24 We also saw examples of pharmacy shopping,
25 patients going to various pharmacies to try to obtain

1 additional opioids, and we then would call the pharmacies
2 and alert them to this problem when we encountered it as
3 well as other red flags that we were concerned about?

4 And it was very seldom in that time period
5 that we heard from pharmacists regarding these types of
6 problems that we were detecting when we checked our
7 prescription drug monitoring database or when we detected
8 other red flags.

9 Of course, to some extent, we are prohibited
10 by privacy laws from sharing too much with anybody
11 outside of our clinical care. So there were instances
12 when we were concerned but could not necessarily
13 communicate that with pharmacists unless it was around a
14 specific prescription.

15 Q. Well, I thought your interactions with pharmacists
16 only revolved around particular prescriptions?

17 A. Yes. My interactions with pharmacists and
18 interactions in general and physicians pertain to the
19 prescriptions that we write for the patient, but in
20 checking the prescription drug monitoring database, what
21 we can see is all the prescriptions for controlled
22 substances that that individual is receiving, which can
23 raise red flags with you, which we can't necessarily
24 discuss with a pharmacist, unless it is our specific
25 prescription that is the prescription of concern.

1 Q. Okay. So you are saying starting in 2013 you were
2 -- it was mandatory to check the PDMP. I think, Doctor,
3 you said that starting in 2013 you were required to check
4 the PDMP before filling a prescription, and at that time,
5 you were getting very few calls that were initiated from
6 pharmacies. Has that changed?

7 A. So let me just clarify my prior statement.

8 Starting in 2013, we set up requirements
9 specifically in my clinic. It wasn't that it was a state
10 mandate that we check the PDMP, but starting at that
11 time -- and I supervise a lot of trainees, residents, and
12 fellows -- it became a requirement in our clinic to check
13 the PDMP before prescribing the controlled substance. It
14 was not mandatory at the state level at that time. It
15 didn't become mandatory in California until later.

16 Q. Do you recall when it became mandatory in
17 California?

18 A. Yes. I believe it became mandatory in California in
19 2018 to have access to the PDMP and shortly after to
20 check the PDMP prior to initiating a new prescription for
21 a controlled substance.

22 Q. Okay. All right. Have you seen a change since 2013
23 in terms of the frequency that you would get calls, calls
24 or electronic communications, communications through
25 pharmacies about particular prescriptions that you or

1 your practice had written?

2 A. Yes. Particularly in the last couple of years, I
3 have seen a much more heightened vigilance around opioid
4 prescriptions on the part of pharmacists, and we have
5 been getting more calls from pharmacists double checking
6 red flags in the past couple of years.

7 Q. All right. And what are the most frequent red flags
8 that pharmacists are identifying when they call where you
9 practice if you are able to answer?

10 A. Yeah. So the most frequent kind of calls we have
11 been getting or getting from pharmacists when they are
12 concerned about a forged prescription, an illegitimate
13 prescription or in the example I gave you, a patient
14 calling in impersonating, potentially impersonating a
15 prescriber.

16 Also, on Tuesday, I received a call from a
17 pharmacist who was concerned about a case of doctor
18 shopping. She had checked the PDMP prior to dispensing
19 Sublocade, which I had prescribed for a patient.

20 It is an injectable form of buprenorphine
21 and she had seen that he had received a hydrocodone
22 prescription from not one but two other prescribers, but
23 I was able to reassure her that he had had a recent
24 surgery, and that the hydrocodone was appropriate in
25 addition to the buprenorphine-Sublocade as a brief

1 analgesic in the context of his surgery and the fact that
2 he had two prescribers was something that we had already
3 seen and investigated and had confirmed that the one
4 prescriber was covering for the other prescriber. It was
5 not a case of doctor shopping.

6 I have had pharmacists call and tell me that
7 the patient came in intoxicated and appeared to be under
8 the influence, and that they were concerned about
9 dispensing opioids or benzodiazepines to that individual.
10 Those kinds of calls we would get.

11 Q. My last general question in this area: Are you able
12 to quantify, you know, calls, inquiries from pharmacists
13 on a weekly or a monthly basis, comparing the present,
14 say, the last two years versus, you know, 2013-2014. I
15 know you probably haven't kept detailed records but sort
16 of from your recollection.

17 A. Yes. I can tell you in the first decade of this
18 century I almost never received a call from pharmacists,
19 and in fact, my first awareness of a patient of mine who
20 was doctor shopping came to my attention because the
21 insurance company sent me a letter expressing concern.

22 This was in the days prior to my having
23 access or even knowing about the PDMP. This was in the
24 early 2000s. I can think of a single instance between
25 2000 and 2012 or '13, in which I received a call from a

1 pharmacist who expressed concern about a patient who
2 appeared to be intoxicated and about whom this pharmacist
3 was concerned and felt uncomfortable dispensing --

4 Q. Okay. In the last --

5 A. -- compared to just this week I have already had two
6 calls from pharmacists specifically relating to opioid
7 prescribing and opioid dispensing.

8 Q. Okay. Couple more general questions, and then, I
9 will take a break from mine and see if counsel want any
10 follow-up.

11 Have you gained an understanding of the
12 separate obligations of doctors and pharmacists regarding
13 opioid prescribing and dispensing, and has your research
14 and teaching included the role of pharmacies in the
15 prescription-opioid epidemic?

16 A. Yes.

17 Q. Okay. If you can elaborate, please.

18 A. I am familiar with the Controlled Substances Act and
19 the fact that every entity and individual in the supply
20 chain has an independent and corresponding responsibility
21 to prevent misuse and diversion and the harms caused by
22 controlled substances.

23 Pharmacies and physicians, in particular,
24 have an independent but corresponding responsibility that
25 depends on their close communication and interaction with

1 each other to the extent that they are able afforded by
2 the law.

3 These independent and corresponding
4 responsibilities are vital because pharmacists and
5 physicians have access to different kinds of information,
6 and without all of those kinds of information, an
7 individual who is misusing or diverting controlled
8 substances could go undetected.

9 So for example, pharmacists have access to
10 whether or not a patient is intoxicated or under the
11 influence when they go to pickup their prescription. The
12 pharmacist has access to information whether that
13 customer paid in cash or traveled a far distance to
14 pickup that prescription.

15 The pharmacist has information as to whether
16 or not that individual is impersonating someone else or
17 using a forged prescription. Those are all things I do
18 not have access to.

19 Correspondingly, I have access to
20 information the pharmacist doesn't have. I have a deeper
21 and broader information of that individual's diagnosis,
22 how they are presenting in clinical care, of their past
23 history. I have access to labs: I have access to urine
24 drug screens?

25 And another really important point regarding

1 this independent but corresponding responsibility between
2 physicians and pharmacists is that physicians really only
3 have access to the information based on one individual
4 patient, whereas pharmacists, and more importantly,
5 pharmacies have access to much more data than an
6 individual physician might, including data about not just
7 patients and their behavior patterns but also
8 prescribers.

9 Pharmacies, for example, have access to
10 data, which would allow them to know whether or not a
11 certain prescriber is prescribing large quantities of a
12 controlled substance prescribing in a pattern that is
13 suggestive of a pill mill, and pharmacies could use this
14 information and create tools to assist pharmacists in
15 detecting red flags.

16 Q. Okay. Has your specific research in teaching
17 included the role of pharmacies in mitigating or
18 addressing the misuse of prescription opioids?

19 A. Yes.

20 Q. Okay. If you could elaborate on that, please?

21 A. So my research has delved into the disease of
22 addiction, which gives me an understanding, an expertise
23 in knowing the kinds of behaviors that people engage in
24 when they become addicted and the kinds of manipulative
25 techniques that they use?

1 And I write about that in my book "Drug
2 Dealer, M.D." prior to being involved in litigation. I
3 have researched and taught on prescription drug
4 monitoring databases and the way that they can and should
5 be used to monitor for misuse and diversion as well as
6 the epidemiologic literature on the impact that checking
7 the PDMP has had on opioid-related misuse addiction and
8 overdose stats.

9 I have published on the PDMP and the
10 importance of checking the PDMP, not just when red flags
11 already exist, but even in cases that's in pristine
12 precisely because a patient's outward appearance can be
13 very different from their internal disease process?

14 And it is very difficult to really know
15 patients' behaviors based on their outward appearance.
16 We do need to check these objective data points, and the
17 PDMP is one of the best tools we have. And I have
18 written about the PDMP prior to being involved in this
19 litigation, and I have researched, and I have taught on
20 the PDMP.

21 So, you know, my research in my 25 years of
22 clinical experience have given me the expertise and
23 knowledge to be able to evaluate the pharmacies' policy
24 and procedures for investigating red flags and have
25 allowed me the expertise to determine whether or not

1 those policies and procedures were adequate.

2 Q. Let me just ask one more follow-up on that:

3 Have you studied the particular policies and
4 procedures of any one of the Defendants in this case? So
5 that would be the specific policies and procedures of
6 Walgreens, CVS, Wal-Mart, Giant Eagle?

7 A. Yes, I have.

8 Q. Okay. Can you elaborate on that, please?

9 A. As detailed in my report, I studied the policies and
10 procedures for investigating red flags and drug
11 utilization review for each of the named pharmacy
12 Defendants and followed how those policies and procedures
13 changed over time, compared that to DEA enforcement
14 actions and the peer-reviewed medical literature on which
15 those regulations should be based and determined whether
16 or not those policies and procedures for those individual
17 pharmacy Defendants were adequate and sufficient to meet
18 their corresponding responsibility according to the
19 Controlled Substances Act.

20 Q. All right. Is this something you wrote about or
21 you just studied? I mean, we will just say pick
22 Walgreens, what your study of Walgreens' policies and
23 procedures over time, is this something you wrote or just
24 studied?

25 A. So my report has an entire section on Walgreens, not

1 just their policies and procedures, their good faith
2 dispensing policy, but how it changed over time, how that
3 compared to the information that was available and should
4 have informed those policies and procedures and,
5 furthermore, what kinds of tools they created to assist
6 pharmacists in detecting red flags and, furthermore, what
7 kind of road blocks they put in place, making it
8 difficult, if not impossible, for pharmacists to do their
9 due diligence and corresponding responsibility to detect
10 red flags. And that's all in my report, your Honor.

11 Q. Okay. And what -- we will just stay with Walgreens
12 because I assume you did the same thing for each
13 Defendant, but let's just focus on Walgreens -- to do
14 this, to generate this portion of your report sort of an
15 examination over time of Walgreens' policies and
16 practices and how they both assisted their pharmacists
17 and in your opinion hindered their pharmacists, imposed
18 road blocks on the individual pharmacists, tracking
19 prescriptions, what exactly did you study or who did you
20 contact to produce that?

21 A. Most of those documents were documents I obtained in
22 discovery. I examined their good-faith dispensing
23 policies and exactly what they identified as the roles
24 and responsibilities of pharmacists, what they identified
25 as red flags that should trigger pharmacists to

1 investigate.

2 I compared -- I looked at DEA enforcement
3 actions that were occurring around the same time to
4 determine whether or not their policies and procedures
5 for detecting red flags were informed by DEA enforcement
6 actions that were occurring, that should have informed
7 those policies and procedures.

8 I investigated the medical literature on the
9 risks, for example, of combining opioids and
10 benzodiazepines and determined when in the medical
11 literature it became known that that was a dangerous
12 combination?

13 And their own policies dictate that the
14 medical literature should inform how red flags are
15 defined and what should be investigated and what
16 pharmacists should investigate?

17 So I looked at whether or not they, in fact,
18 utilized the medical literature and allowed that to
19 inform their policies and procedures and the tools that
20 they created for detecting red flags. I looked at things
21 like their relationship with lobbying organizations, the
22 National Association of Chain Drug Stores, for example,
23 and how they interacted with and took the advice or
24 didn't of those kinds of organizations.

25 I looked at consulting organizations that

1 they interacted with and how they took or didn't take the
2 advice of those consulting organizations so basically
3 looking in aggregate at all of the information that they
4 had, that could have and should have informed their
5 creation of policies to assist pharmacists.

6 Q. Okay. Thank you, Doctor.

7 THE COURT: I think I will take a break from
8 my questioning and maybe no more than 10 minutes for each
9 side to ask any follow-up in what I have asked.

10 So I think I will let the Defendants go
11 first since it was your motion challenging Dr. Lembke.
12 So who would like to question Dr. Lembke from the
13 Defendants.

14 MR. BUSH: Your Honor, it is Graeme Bush
15 from Zuckerman Spaeder. I don't know if you can see me?

16 THE COURT: Yes, Graeme, I see you.

17 MR. BUSH: I will be conducting the
18 examination of Dr. Lembke for the defense, so I want to
19 follow up on a couple of things.

20 EXAMINATION BY COUNSEL ON BEHALF OF DEFENDANT CVS

21 BY MR. BUSH:

22 Q. Dr. Lembke, good morning. It is almost as early for
23 you as me. I am in the Mountain Time Zone.

24 A. Good morning.

25 Q. So one of the questions that Judge Polster asked you

1 related to your interaction with pharmacists, and I want
2 to ask some follow-up questions in that area. One of the
3 focuses of the questioning was whether your interactions
4 related to particular prescriptions.

5 And in addition to that, there were some
6 circumstances where information came to your attention
7 and you under those circumstances were called upon to
8 assist and about what kinds of information you could
9 disclose beyond the particular prescription that you had
10 written. Is that right?

11 A. Yes.

12 Q. Okay. So the interactions that you had, those
13 related to the prescription. You did not conduct any
14 kind of investigation about what other due diligence the
15 pharmacists may have done before calling you or after
16 calling you.

17 A. I am not sure I understand the question.

18 What do you mean by conducting an
19 investigation for that individual pharmacist? Did I ask
20 them what else they had done?

21 Q. When you're asking about a particular prescription,
22 your are finding out what that pharmacist is interested
23 in about that prescription, not what other due diligence
24 the pharmacist may have done other than calling you?

25 A. No, that's not correct.

1 Q. All right.

2 A. These are often conversations between medical
3 professionals where, again, to the extent that we are
4 able, given privacy laws, where we share our information.

5 When the system is working as it should, we
6 have a conversation about the patient and their
7 prescription and the dispensing and where we have
8 overlapping concern.

9 So that conversation might often entail
10 other things that the pharmacist has observed or other
11 information that the pharmacist has access to. You know,
12 in instances when I can get that kind of information is
13 incredibly helpful.

14 Q. All right. So one of the things you testified about
15 has to do with your review policies and procedures?

16 A. Yes.

17 Q. And it is accurate, is it not, that the policies and
18 procedures that you reviewed in connection with your
19 report in this case are only the policies and procedures
20 that were provided to you by Plaintiffs' counsel?

21 A. That is correct.

22 Q. And they were only the policies and procedures that
23 related to the Defendants in this case?

24 A. Correct.

25 Q. And you are not able to make any comparison between

1 these policies and procedures of the Defendants in this
2 case and policies and procedures that may or may not have
3 been in place at other pharmacy companies?

4 A. Not beyond my own professional experience,
5 interacting with pharmacists from different
6 pharmacies.

7 Q. And you have not conducted any kind of systematic
8 study or analysis of any pharmacy or pharmacy chain that
9 isn't a Defendant in this case?

10 A. That's correct.

11 Q. And so the analysis of the policies and procedures
12 that you have done in this case as an analysis, that was
13 done specifically for the purpose of formulating opinions
14 in this case?

15 A. As pertains to the evolution of policies and
16 procedures for pharmacy Defendants over time, yes.

17 Q. You also testified about corresponding
18 responsibility, and first of all, you are not a lawyer.
19 That's right, correct?

20 A. That is correct.

21 Q. You would agree with me that the prescriber has a
22 responsibility to write a prescription that is for a
23 legitimate medical purpose in the usual course of his or
24 her practice?

25 A. Yes.

1 Q. And the pharmacist has a different obligation called
2 a corresponding responsibility to determine whether the
3 doctor actually lived up to that obligation?

4 A. Well, that is part of the pharmacist's role, but the
5 pharmacy, more broadly, has a responsibility to create
6 policies and procedures to mitigate the risk of misuse
7 and diversion and harm from dispensing.

8 Q. That's not in the language of the corresponding
9 responsibility regulation, is it?

10 A. I believe that it is, if not in the CSA, certainly
11 in many DEA enforcement actions.

12 Q. All right. And just to reiterate, you are not a
13 lawyer?

14 A. No, I am not a lawyer.

15 Q. So I think only one other subject that I want to ask
16 you some questions about, Dr. Lembke:

17 You have not had any -- actually withdrawn.
18 Let me say it a different way.

19 You have not been involved in whatever
20 training a pharmacist gets with respect to his or her
21 corresponding responsibility. Is that right?

22 A. Can you clarify what you mean by "have been involved
23 with"?

24 Q. Sure. You understand that pharmacists are trained
25 or you believe that pharmacists are trained in

1 corresponding responsibility at pharmacy school?

2 A. Yes.

3 Q. But you haven't been involved in teaching any of
4 those courses?

5 A. I have not been involved in teaching pharmacists in
6 pharmacy school, no.

7 Q. And you haven't taken any of those courses?

8 A. No, I have not.

9 Q. And you haven't taken any continuing education
10 courses that pharmacists might have with respect to their
11 corresponding responsibility?

12 A. Well, I have to qualify that answer because much of
13 the education that pharmacists have received in the past
14 two decades regarding the legitimate use of opioids is
15 similar to the education that physicians have received
16 and has been influenced in a similar way by opioid
17 manufacturers.

18 So in fact, I am familiar with education
19 around opioids that pharmacists have received in the
20 last two decades because it is very similar to the types
21 of education received by physicians in the same time
22 period.

23 Q. And if you haven't taken those courses, how do you
24 know how similar it is or how dissimilar it is,

25 Dr. Lembke?

1 A. Yeah, because that's part of the research that I
2 have done, that I have investigated what those courses
3 entailed, what kind of power points were used, what kind
4 of educational messages were included in their
5 curriculum. So I've looked into that.

6 Q. So do you recall that in your deposition at Track
7 One -- and you know the difference between the tracks in
8 these cases -- but I assume you know the differences?

9 A. Yes, I do. Thank you.

10 Q. Do you remember testifying that you knew that
11 pharmacists had a certification and have schooling and a
12 certification process, but you didn't know a whole lot
13 more about it than that?

14 A. Yes. I specifically recall that testimony.

15 Q. And do you also recall that you are agreeing that
16 you weren't a pharmacist in stating that you haven't
17 studied what pharmacists go through?

18 A. Yes. And what I meant by that is, I don't know the
19 specifics of pharmacy certification and education I don't
20 know. Unlike my familiarity with medical training and
21 physician training, I am not intimately familiar with the
22 hoops that pharmacists jump through to get to be a
23 pharmacist.

24 But I will add that medical education and
25 pharmacy education is ongoing with continuing education

1 beyond pharmacy school, and that is the part of the
2 pharmacists' education that I am familiar with and that I
3 had studied and which, as I have said, has mirrored a
4 physician education in the last two decades vis-a-vis
5 opioids.

6 Q. Well, when you say it's your position, you have just
7 also said that you agreed that you didn't know what
8 pharmacists go through, and you don't know a whole lot
9 more than they get a certification and have some
10 schooling. So how can you have the kind of detailed
11 information that you have just talked about?

12 And all I am talking here is specifically
13 what pharmacists are trained in, not what they ought to
14 be trained in.

15 A. I know that. I understand. Let me see if I can
16 clarify.

17 So medical education, like pharmacy
18 education, is long. It starts with school, and then you
19 graduate, and you get your degree or your certification,
20 and then you go out into practice? And in practice,
21 there is a process of ongoing education that spans one's
22 entire career.

23 When I said in prior deposition I was not
24 familiar with pharmacist school and pharmacy education,
25 it is just that. I am not familiar how pharmacists are

1 trained in pharmacy school, but after they graduate and
2 are in practice and the recipient of different forms of
3 education, I have studied that education around opioids,
4 the education of, and I am familiar with the types of
5 education that pharmacists have received, pharmacists who
6 are working in pharmacies have received as part of
7 they're maintenance of education or equivalency.

8 Q. So the answer that I asked you about before in Track
9 One was in response to a question. What knowledge do you
10 have about pharmacy training? It was not limited to
11 pharmacy school. Do you recall that?

12 MR. WEINBERGER: Objection, your Honor.

13 A. Yeah --

14 THE COURT: I will let her answer the
15 question. We are about at the end of the time.

16 MR. BUSH: And I am almost done, your Honor.
17 I would be done anyway if you told me I was, but I am
18 almost done, your Honor.

19 A. So my interpretation of the question at that time --
20 and I remembered it vividly -- was that I was being asked
21 about pharmacy school, and I don't have much familiarity
22 with pharmacy school.

23 So for example, I can tell you that
24 physicians go to medical school. They get their license.
25 They sit for their board. They have board certification.

1 I don't know what the various hoops are that pharmacists
2 go through prior to becoming a pharmacist and working in
3 a pharmacy. I don't know how long their school is. You
4 know, I don't know what the tests are that they have to
5 take.

6 So my answer has not changed, but I
7 understood that question several years ago to pertain
8 specifically to pharmacy school.

9 Q. I won't belabor the point, and I think the record
10 will reflect what the questions were?

11 MR. BUSH: But with that, your Honor, I am
12 done.

13 THE COURT: Thank you, Mr. Bush. Is
14 there someone from the Plaintiffs who wants to ask
15 follow-ups?

16 MR. WEINBERGER: Your Honor, this is Peter
17 Weinberger on behalf of the Plaintiffs. I have no
18 questions.

19 THE COURT: Okay. All right. Then I will
20 go back to mine, Doctor.

21 FURTHER EXAMINATION BY THE COURT

22 BY THE COURT:

23 Q. I was asking you about your study of the prescribing
24 practices and policies of each of the four Defendants,
25 and you were describing that.

1 Was that study and research done only as
2 part of your work as a -- as an expert in this
3 litigation, or had you done some of that research before
4 this litigation as part of your general research?

5 A. That research was primarily done since I have been
6 involved in this litigation.

7 Q. Okay. That's what I figured, but I wanted to
8 clarify.

9 As part of your research, either for this
10 litigation or in general, have you looked into whether
11 there exists any cooperative efforts between
12 manufacturers and pharmacies to ensure access to
13 prescription opioids for patients?

14 A. Yes.

15 Q. Okay. If you can describe what that has been,
16 please?

17 A. In my research, I have found that pharmacy
18 Defendants -- opioid manufacturers and opioid
19 distributors collaborated together to promote opioids.

20 They did that through collaborative
21 educational efforts of pharmacists, through collaboration
22 around coupons and saving cards, through collaborations
23 with direct-to-pharmacist advertising and also
24 direct-to-patient consumer advertising so, for example,
25 creating patient facing pamphlets, not just in

1 collaboration with manufacturers, but also in
2 collaboration with pro opioid lobbying groups often
3 funded by manufacturers.

4 Q. All right. I would like you to detail this a little
5 more. What have you learned about these specific
6 cooperative efforts with respect to education of
7 pharmacists? How did the manufacturers of the pharmacies
8 cooperate and collaborate in education of pharmacists and
9 then coupon and saving card programs and then this
10 advertising?

11 A. So pharmacy Defendants for a fee offered to promote
12 and advertise specific opioid products to their
13 pharmacists and also to patients.

14 Some pharmacy Defendants allowed, for
15 example, Perdue drug reps to come into pharmacy stores
16 and interact directly with pharmacy managers. Pharmacy
17 Defendants collaborated with the American Pain Foundation
18 and with the Pain Care Forum. These are loosely
19 affiliated pro opioid lobbying groups largely funded by
20 opioid manufacturers to, for example, create a patient
21 facing pamphlet to, quote unquote, educate patients about
22 the appropriate use of opioids in the treatment of pain.

23 Pharmacies worked together with opioid
24 manufacturers to create so-called opioid super stores
25 where opioids would be more readily dispensed without

1 questioning prescribers.

2 Q. Okay. Can you detail for me, explain to me what an
3 "opioid super store" is? Is this a particular pharmacy,
4 or is it something else?

5 A. It is a particular pharmacy at which opioids will be
6 stocked in a way that makes them readily available to
7 patients, but opioid super stores really go beyond that.

8 Some of these opioid super stores in my
9 opinion became the equivalent of pharmacy pill mills
10 where they promise opioid manufacturers, for example, not
11 to question prescriptions but to make it guaranteed that
12 a patient showing up there could get that prescription.

13 This was all done in the name of making sure
14 that patients got opioids who needed them, but in fact,
15 the volume of prescribing at these stores really suggests
16 that there was misuse and diversion.

17 There was an instance in which one of the
18 opioid manufacturers promised to resupply one of the
19 pharmacies who had lost prescription -- lost some of
20 their supply -- if they lost their supply through
21 diversion. So even when there was known diversion, I
22 have reviewed documents stating that pharmacy would be
23 immediately resupplied.

24 Q. All right. Let me just pickup on that.

25 Was that particular pharmacy a pharmacy of

1 one of the Defendants in this case or some other
2 pharmacy?

3 A. Yes, yes. And that's in my report, your Honor. I
4 would be happy --

5 Q. Which company was this?

6 A. I believe it was Perdue, and I really would have to
7 look at my report to see which pharmacy it was.

8 Q. But do you recall it was one of the Defendants in
9 this case?

10 A. Yes.

11 Q. And these super stores that you've described, were
12 any of -- any of these so-called super stores pharmacies
13 of any of the Defendants in this case?

14 A. Yes.

15 Q. I guess I want to follow-up.

16 Have you examined, done any focused
17 examination of the pharmacies operated by the four
18 remaining Defendants in this case? That's Walgreens
19 Wal-Mart, CVS, and Giant Eagle, pharmacies operated by
20 those four Defendants in the two counties we are focusing
21 on. The two Plaintiffs, as you know, are Trumbull County
22 and Lake County, the Northeast part of Ohio.

23 Have you done any research on practices,
24 policies of the pharmacies that the four Defendants
25 operated in these two counties?

1 A. My research is based on national policies in
2 aggregate. I have not looked at specific pharmacies in
3 Lake and Trumbull County.

4 Q. All right. Have you formed a specific opinion based
5 upon your medical knowledge and practice and the research
6 you've done in this case as to whether the policies and
7 practices of any of the four individual Defendants was
8 sufficient and adequate to detect and ameliorate
9 diversion of prescription overwrites? Have you formed an
10 opinion?

11 A. Yes, I have.

12 Q. And is your opinion -- do you have a specific
13 opinion as to each of the four Defendants?

14 A. Yes.

15 Q. All right. Is that opinion based on your research
16 and your study of the literature and the documents?

17 A. Yes.

18 Q. All right. I guess I am going to ask you what that
19 opinion is and do it by Defendant because again, as you
20 know, in a court of law, the jury has to consider the
21 evidence against each Defendant separately, and I would
22 not allow anyone just to make a general blanket opinion
23 undifferentiated and say, well, this applies to everyone
24 and just a blanket opinion. That won't cut it in my
25 Court, and I doubt any other one.

1 So let's start with Wal-Mart. What is your
2 opinion on Wal-Mart?

3 MR. WEINBERGER: Your Honor, can I
4 interject? Do you mind if Dr. Lembke refers to her
5 report?

6 THE COURT: No, not at all, not at all.

7 BY THE COURT:

8 Q. And you know, I -- probably shorthand -- but I want
9 to crystallize it, what her opinion is, and if you
10 specifically state it in your report, you can highlight
11 where it is in your report.

12 A. Well, my report includes all of the supporting
13 evidence that contributed to my opinion. My opinion is
14 that for each of the pharmacy Defendants individually
15 they lacked policies and procedures to adequately
16 investigate red flags during the first decade or more of
17 the opioid epidemic, and even after certain policies were
18 adopted, they were inadequate.

19 They could have and should have used their
20 own data to assist pharmacies in identifying prescriber
21 red flags and they furthermore more implemented
22 counter-productive measures disempowering pharmacies from
23 enacting their corresponding responsibility such as time
24 limits and incentive programs.

25 Q. And this is all spelled out in your report?

1 A. Yes, by individual pharmacy Defendants.

2 MR. WEINBERGER: Your Honor, for purposes of
3 the record, the report begins to address the specifics as
4 to each of the Defendant pharmacies at page 99 and
5 continues for about 20 or 25 pages thereafter.

6 THE COURT: Okay. Thank you,
7 Mr. Weinberger.

8 BY THE COURT:

9 Q. And your last answer, you referred to the first
10 decade.

11 A. First decade or more.

12 Q. Or more. What years are you talking about when you
13 make that reference?

14 A. Approximately 1999 to approximately 2013-2015.

15 Q. So it is really closer to a decade and-a-half --

16 A. Yes.

17 Q. -- if you are using that time frame. Okay.

18 All right. I have to admit, I haven't read
19 your report page by page.

20 Did you research, for example, whether the
21 corporate practice required individual pharmacists to
22 consult the PDMP before dispensing -- before filling a
23 particular prescription?

24 A. Yes, your Honor. That was a specific focus of my
25 research, and my report includes detailed chronology

1 around PDMP checking and what the corporate policy was
2 regarding the PDMP in addition to studying OARRS, Ohio's
3 PDMP, and what their regulations and policies were and
4 how, in my opinion, regarding what pharmacy Defendants
5 could have and should have done regarding requiring
6 pharmacists to check the PDMP in order to fulfill their
7 corresponding responsibility compared to what pharmacy
8 Defendants actually did in that regard.

9 Q. Did your research and study and report include the
10 policies, practices, and procedures with respect to
11 identifying red flags and what, if any, checking should
12 be done before the prescription would be filled?

13 A. Yes, your Honor. In detail in my report, I outlined
14 what the, for example, pharmacy operation manuals, what
15 the training, what the mandates were from the corporate
16 level to individual pharmacists for each pharmacy
17 Defendant regarding what they should be doing in checking
18 for red flags as well as, your Honor, information on
19 prohibiting pharmacists from taking certain actions that
20 pharmacists themselves felt would be important for
21 preventing --

22 Q. Can you elaborate on that?

23 What did you identify were examples of
24 policy for pharmacists, for example?

25 A. For example, as I said before, what pharmacies have

1 access to, which physician prescribers do not, is
2 prescriber level data, that is to say, which prescribers
3 out there are essentially pill mill doctors issuing
4 prescriptions not in the course of usual medical practice
5 and not for a legitimate medical indication.

6 Pharmacists and pharmacies have access to
7 that information; physicians do not. And there is
8 evidence showing that pharmacy Defendant pharmacists at
9 times wanted to have blanket refusals for dispensing for
10 certain prescribers whom they had sufficient evidence to
11 identify as pill mill doctors?

12 And they were prohibited by their higher ups
13 in their pharmacies from doing that and told that they
14 need to evaluate each prescription on an individual level
15 when it comes, even in the case of known pill mill
16 doctors.

17 So even though the pharmacy -- the
18 pharmacists had the ability to look at that data and use
19 that data to help pharmacists meet their corresponding
20 responsibility, they did not do so.

21 Q. You have used the term "red flags," and I think you
22 identified a few of them, and you gave examples.

23 How did you come up with your list of red
24 flags?

25 A. My list of red flags is a combination of my clinical

1 experience, 25 years of seeing patients misusing and
2 getting addicted to and diverting controlled prescription
3 drugs. It is also based on DEA enforcement actions. It
4 is also based on the peer-reviewed literature, for
5 example, the evidence showing that combining
6 benzodiazepines and opioids is a very dangerous
7 combination?

8 And it is also based, in part, on the
9 material produced by pharmacy Defendants themselves and
10 their collaborators like the National Association of
11 Chain Drug Stores, indicating a very acute awareness on
12 the part of pharmacy Defendants about what they should be
13 looking for and what constitutes red flags?

14 And my opinion is based on the large
15 discrepancy between what pharmacy Defendants knew they
16 could and should do and what they actually did to assist
17 pharmacists in investigating red flags.

18 So for example, in my report, I talk about a
19 meeting by the National Association of Chain Drug Stores,
20 an organization to which the pharmacy Defendants in this
21 case belonged and have National Association of Chain Drug
22 Stores created a task force and said "we need to be more
23 proactive about determining these red flags and
24 investigating them."

25 And it outlined the three groups of red

1 flags that could be attributable to patient consumers,
2 that could be attributable to prescribers, and that could
3 be attributable to pharmacists, and they talked about the
4 creation of a surveillance system, policies and
5 regulations, that could detect these red flags?

6 And pharmacy Defendants in this case -- and
7 I outlined one pharmacy Defendant in particular --
8 outright rejected the recommendations of their own
9 organization.

10 Q. All right. As you know, there is no Government
11 published list of red flags that say "look, these are the
12 -- these are the things you must look for or check for."

13 My question is: In your research, your 25
14 years of clinical practice, research and study for this
15 case, is there significant disagreement over what is and
16 what isn't a red flag, or is it just -- are there a
17 number of red flags, which almost everyone understands
18 are suspicious and should be checked if my question is
19 intelligible?

20 I just want to know, is there a consensus or
21 is there disagreement, a significant majority and
22 minority opinion?

23 A. Yes. I would say there are some red flags for which
24 there is absolute clear consensus, no controversy
25 whatsoever. I would add that red flags can emerge over

1 time. And so part of the responsibility of everybody in
2 the opioid supply chain is to pay attention to emerging
3 red flags?

4 And I would also assert that there can be
5 some degree of controversy about a portion of those red
6 flags and whether or not they constitute red flags or the
7 extent to which they constitute red flags or how that red
8 flag should be investigated.

9 Q. All right. I am about done.

10 I would like you to -- if you can identify
11 the red flags that you say there is general consensus,
12 that virtually everyone agrees that these things -- you
13 have got to check for these things, or if you see one of
14 these things you, are really being derelict if you don't
15 do some follow-up or checking.

16 A. So, your Honor, I could do that from memory, but I
17 might leave one or two things out.

18 Q. If you have identified it specifically in your
19 report, that's fine.

20 A. Yes. I do identify it multiple places specifically
21 in my report. I don't discuss in my report which red
22 flags there is more consensus around than others. I
23 don't do that.

24 It sounds like that's what you are asking me
25 to do now.

1 Q. Right. I would like to know, if you can say, all
2 right. Here are the five or ten consensus red flags that
3 in your years of practice and your study and your
4 research virtually everyone agrees that if you see
5 something, one of these, you ought to start asking some
6 questions.

7 A. Yeah. So I would say that consensus red flags --
8 and again, it is really important to keep in mind a red
9 flag doesn't mean the pharmacist will not dispense. A
10 red flag means this is something a pharmacist needs to
11 investigate.

12 Q. Right. There may be a very good reason like the one
13 you identified where you had a patient who had chronic
14 pain but also had surgery, and that explained it.

15 So that's what we are talking about,
16 something that needs checking.

17 A. So the consensus red flags are a patient who appears
18 to be under the influence of a controlled substance at
19 the time that they present to the pharmacy or for that
20 matter to the prescribing doctor?

21 But specific to pharmacies and pharmacists,
22 I think consensus red flags include traveling a
23 significant distance to fill a prescription, paying
24 in cash, behavior consistent with being under the
25 influence.

1 Other patient-related red flags that have
2 been described around which I believe there is consensus
3 is large numbers of patients, you know, lining up in a
4 pharmacy to get specific prescriptions, all of which have
5 been written in the same way.

6 Consensus red flags, really a cross
7 dispensing broadly is dangerous drug-drug combinations.
8 So those dangerous drug-drug combinations often emerge
9 over time. They are not necessarily known prior to, you
10 know, the FDA approving that drug, but once they have
11 been out in the market, they are detected to be a
12 dangerous combination.

13 And then, many times the first alert comes
14 from pharmacies and pharmacists and then trickles in the
15 opposite direction to prescribers when they are alerted
16 by pharmacists that it is a dangerous drug-drug
17 combination, and specifically with opioids, that's
18 benzodiazepines, sedatives, and opioids in combination,
19 those -- because that's a commonly -- that's a
20 combination that people who are addicted use and also
21 because it is a deadly combination, because sedatives and
22 opioids work synergistically to decrease heart rate,
23 decrease respiration, and contribute to the increased
24 overdose risk.

25 Those are often referred to as cocktails in

1 the DEA enforcement literature.

2 And then, other red flags from the pharmacy
3 level are excessive volume and rate of growth of
4 controlled substances at that pharmacy. You know, how to
5 quantify a concerning rate of growth is -- there is
6 probably some debate about that, but it is very clear
7 that some pharmacies engaged in highly prolific
8 dispensing outside of what could be appropriate medical
9 use.

10 Q. All right. And --

11 A. Other ones -- I'm sorry.

12 Q. Do you know --

13 A. Sorry. Other ones include doctor shopping, so all
14 of the kinds of red flags that you would get from
15 checking the prescription drug monitoring database,
16 doctor shopping, pharmacy shopping.

17 The PDMP is also very useful for dangerous
18 drug-drug combinations because often patients will get a
19 different prescription from different prescribers, so
20 again, the individual prescriber may prescribe an opioid
21 and not know that individual is also getting a
22 benzodiazepine from somebody else or a stimulant from yet
23 somebody else. There is Soma from their orthopedist, so
24 checking the PDMP is really vital for assessing dangerous
25 drug-drug combinations as well.

1 Q. Some of the red flags, many or most of the red
2 flags, the consensus red flags you've identified are
3 things that the individual pharmacist would be observing
4 and should follow up and question.

5 Am I correct, you know, excessive volume and
6 rate of growth of opioid prescriptions at a particular
7 pharmacy, that would be something, would it not, that
8 needs to be monitored at the corporate level because the
9 problem there could be you have got an individual
10 pharmacist that is just -- that's become a pill mill, and
11 if that's the problem, obviously, the pharmacist will not
12 be checking on herself or himself. Wouldn't that be
13 something at the corporate you would see?

14 You have got 2,000 pharmacies over the
15 country and you can see generally what percentage their
16 business is prescription, opioids, and how it has changed
17 over time, and if you have five or ten that seem off the
18 charts, you ought to look.

19 Isn't that something that would need to be
20 checked at the corporate level?

21 A. Your Honor, I would argue that all of these red
22 flags need to be facilitated at the corporate level. It
23 cannot be left to the individual pharmacist to
24 independently check all of these red flags without
25 support and tools created at the corporate level and

1 sufficient time granted at the corporate level. These
2 are labor intensive investigations.

3 I think the average pharmacist has 1.5
4 minutes to fill a prescription. At the corporate level,
5 if environment is not created to assist pharmacists in
6 this work and the appropriate tools are not given to
7 pharmacists and the appropriate guidance, then, that's
8 not an adequate infrastructure for preventing misuse and
9 diversion.

10 Q. Well, has your research, study, experience,
11 identified what types of tools and support the
12 corporation needs to give to its individual pharmacists
13 to enable them to do their job?

14 A. That certainly is implied in my report, yes.

15 Q. You are saying it is implied. But I am not
16 sure what that means. Have you detailed it in your
17 report?

18 A. I have detailed in my report that pharmacists need
19 to be given the time to investigate red flags. They need
20 to be incentivized to investigate red flags. They are
21 currently, commonly incentivized to dispense as many
22 pills as possible in a given day, in the shortest amount
23 of time to meet certain quotas or prom -- what's called
24 promise times or bonus requirements.

25 They need to be given access to not just the

1 PDMP, which should be mandatory or required, in my
2 opinion, for pharmacists to check prior to dispensing and
3 which is labor intensive?

4 So they need to be given sufficient time and
5 infrastructure and tools to check the PDMP, but also at
6 the corporate level, the pharmacy Defendants have the
7 ability to access their own databases to check red flags
8 for prescribers, and pharmacists should not -- should
9 also have access to that information.

10 And of course, their investigation around
11 investigating red flags needs to be much more robust,
12 informed by the literature, the scientific literature,
13 informed by DEA enforcement acts.

14 There really isn't adequate policies and
15 procedures or support of pharmacists in place in order
16 to allow them to uphold their corresponding
17 responsibility.

18 Q. Okay. Doctor, what do you think are the limits of
19 your expertise with respect to the policies and
20 dispensing practices of the four pharmacy Defendants?

21 A. I haven't done any quantitative analyses. I haven't
22 looked at proportion of blame in any kind of quantitative
23 way. I haven't specifically looked at individual
24 pharmacies or pharmacists in Lake or Trumbull County.

25 Q. And I think, as Mr. Bush highlighted, you haven't

1 studied any of the other pharmacies which, of course,
2 exist --

3 A. That's right, and I am not a lawyer, and I am not a
4 pharmacist.

5 Q. -- and compared what, if anything, they are doing
6 with the four Defendants here.

7 A. That's right.

8 Q. Do you believe there is a difference between a
9 prescription that is not written for legitimate medical
10 purpose and a prescription that is diverted, and if so,
11 what would be the difference? So the difference between
12 a prescription not written for legitimate medical purpose
13 and a prescription that is diverted.

14 A. My understanding of diversion is that it is actions
15 that allow a prescription to get into the hands of an
16 individual for whom it was not intended. Sometimes a
17 prescription that is not written for legitimate medical
18 purpose can be an act of diversion.

19 Other times a prescriber who is well
20 intentioned but duped might believe they are writing a
21 prescription for a legitimate medical purpose when, in
22 fact, that is not an evidence-based indication, or that
23 prescriber may not have access to information that would
24 allow them to make a judgment about whether or not that
25 would be a legitimate medical purpose.

1 So I feel like those are overlapping venn
2 diagrams.

3 Q. Let me see if I can flush this out a bit.

4 So if I have a condition that justifies a
5 prescription opioid and my doctor examines me and
6 prescribes that prescription to me and somehow that
7 prescription gets to you, Doctor, and you fill it and you
8 get the opioids, that's an example of a prescription that
9 was written for a legitimate medical purpose but was
10 diverted. Would that be fair?

11 A. Yes, assuming that the original prescription was for
12 legitimate medical purpose.

13 Q. Right. Okay. I have a legitimate medical need for
14 it, and the doctor believes I have a legitimate medical
15 need, and he or she writes it for me, and the
16 prescription ends up in your hands --

17 A. Uh-huh.

18 Q. -- and has been diverted. How it got diverted,
19 that's an issue, but it is clearly diverted --

20 A. Yes.

21 Q. -- whereas if a prescription is written for me and,
22 in fact, I don't have a legitimate medical need for that
23 prescription opioid, that would be a prescription that is
24 not written for a legitimate medical purpose, right?

25 A. That's right.

1 Q. There are many ways that that could come about, but
2 that would be a prescription that is not written for a
3 legitimate medical purpose.

4 A. That's right.

5 Q. And sometimes there is an overlap. You can have one
6 but not the other. You could have both.

7 THE COURT: Okay. All right. I think that
8 that covers what I wanted to cover, and we have got a few
9 minutes. I guess, Mr. Bush, if you have a few
10 follow-ups, and Mr. Weinberger, if you have any, and then
11 we will be concluded.

12 MR. BUSH: Thank you, your Honor.

13 FURTHER EXAMINATION BY COUNSEL ON BEHALF OF
14 DEFENDANT CVS

15 BY MR. BUSH:

16 Q. You testified, Dr. Lembke, I believe that a number
17 of the policies and procedures that you've addressed in
18 your report evolved over time. Do you recall that?

19 A. Yes.

20 Q. And you also said that red flags, some red flags
21 evolved over time as well.

22 A. Yes.

23 Q. And with respect to the PDMP, I think you testified
24 earlier this morning that the Stanford Clinic did not
25 require consultation of the PDMP by the prescribers in

1 2013. Is my memory right on that?

2 A. Yes, that's right.

3 Q. Your opinion in this case, however, is that the
4 pharmacy Defendants should have implemented a mandatory
5 PDMP requirement much earlier than 2013, right?

6 A. I think in my report I do say that they should have
7 made it mandatory. I believe that it should be mandatory
8 for pharmacists. I can't remember what date I assigned
9 to that, if any.

10 Q. Well, let me ask you some questions about the red
11 flags that you went through in response to Judge
12 Polster's questions.

13 You would agree, wouldn't you, that some of
14 the red flags that you identified might not really be red
15 flags because of what the pharmacist knows about the
16 patient, knows about the Doctor, knows about the
17 circumstances of the prescription that is being presented
18 to that pharmacist?

19 A. Yes. I would agree with that.

20 Q. And you would agree that a pharmacist has an
21 independent professional obligation and responsibility
22 not to fill prescriptions that were not written for a
23 legitimate medical purpose. Sorry for the double
24 negative.

25 A. Yes.

1 Q. And likewise, individual pharmacists have a
2 professional responsibility and a legal responsibility to
3 comply with his or her corresponding responsibility?

4 A. I would agree with that, but what I emphasize in my
5 report is that, if the corporate infrastructure is not in
6 place to give the pharmacist the necessary tools to enact
7 and uphold their corresponding responsibility, it becomes
8 impossible for the pharmacist to do that.

9 Q. You also talked about and said something in the
10 context of corporate action, but the pharmacist does have
11 an incentive to live up to his or her professional
12 obligations and legal obligations because if she doesn't,
13 she could lose her license.

14 A. Well, part of the issue there is that pharmacists
15 were miseducated about the evidence-based use of opioids
16 by opioid manufacturers, collaborated with corporate
17 pharmacy Defendants.

18 And so just as with doctors exercising their
19 clinical judgment and their medical judgment requires
20 having access to true information about legitimate
21 medical use of opioids and having an infrastructure and
22 environment that allows them to do that.

23 And there were significant, you know, my
24 research showed me that there were significant
25 consequences professional, adverse professional

1 consequences for pharmacists who complained about having
2 inadequate time to safely dispense opioids and who, when
3 suggesting, for example, that certain prescribers should
4 have blanket refusals, that that was essentially rejected
5 by corporate, and they were told that they had to
6 continue to dispense.

7 So yes, in some ideal world, pharmacists
8 would be able to exercise their judgment, but if their
9 judgment isn't informed by the information and isn't
10 supported by the environment that they live in, I
11 don't think we can expect that pharmacists, except for a
12 few martyrs, would be able to exercise that
13 responsibility.

14 Q. If a pharmacist knew that a prescription was written
15 by a doctor or another prescriber and it was not written
16 for legitimate medical purpose, the pharmacist would have
17 an incentive not to fill that prescription, regardless of
18 any of the other information that you are talking about
19 here because she could lose her license.

20 A. I disagree with your use of the word "incentive"
21 there. I would say the pharmacist has a responsibility
22 not to dispense, but in the face of all the other
23 incentives from the corporate level, it can be very hard
24 for the individual to go against the tide.

25 Q. Well, to go back to the PDMP for a second, I know

1 you've expressed some opinions about when pharmacy
2 companies should have mandated that and under what
3 circumstances pharmacy companies should have mandated
4 their pharmacists consult a PDMP, but you have done no
5 evaluation whatsoever to determine how often pharmacists
6 at each of the pharmacy Defendants actually consulted the
7 PDMP?

8 A. I haven't done any granular analysis at the
9 individual pharmacist level, that's correct.

10 Q. Regardless whether or not the company had a policy
11 that mandated it, it may well be the case that the
12 pharmacist did consult the PDMP in appropriate
13 circumstances?

14 A. In my 25-year clinical experience, the number of
15 times I have detected red flags on the PDMP for my
16 patients when the pharmacy did not is very high, so it
17 has not been in my experience until the last couple of
18 years that pharmacists are more regularly checking the
19 PDMP, and the material that I've looked at would attest
20 to that as well given that, uh-huh.

21 Q. Sorry. To my question though was whether you have
22 in this case, in the two counties that are the Plaintiffs
23 in this case, you haven't evaluated whether the
24 pharmacists at the pharmacies, the pharmacy Defendants
25 actually consulted the PDMP in appropriate circumstances.

1 You have not done that analysis.

2 A. Not at the individual pharmacy level, no.

3 Q. I want to generally stay away from individual
4 Defendants in this examination, but I did want to ask you
5 one question that was CVS specific.

6 And I don't know if I told you this at the
7 outset, but I do represent CVS.

8 When you were -- this has to do with your
9 opinions and testimony about what you consider to be
10 cooperative efforts with the manufacturers and the
11 distributors to enhance access to opioids. That's the
12 general subject matter.

13 And you cited a variety of things that you
14 believe showed collaboration, and you focused, as a
15 result, I think, of Judge Polster's questions on super
16 stores, but as I read the report, you have cited one
17 document, an educational document that related to CVS,
18 and that was the only thing you had cited to show CVS
19 collaboration. And I want to ask you about that
20 document.

21 It was an educational services document. It
22 I think was produced by Incess, not by CVS and you
23 characterized that document as "prescribing a promotional
24 campaign that could be washed by CVS-Caremark pharmacies
25 on behalf of selected opioid manufacturers, "and that

1 "this document illustrates that CVS-Caremark was in the
2 business of promoting opioids, not just dispensing them."

3 Do you remember that general part of
4 your opinion or generally remember that part of your
5 opinion?

6 A. Yes.

7 Q. And I can pull that document up if you don't recall
8 it, but do you have any evidence or information to
9 suggest that there was ever an opioid product that was
10 promoted pursuant to this educational program that CVS
11 was talking about?

12 A. So my recollection of my report -- and I really need
13 to look at my report to answer this question -- is that I
14 cite more than one document. I cite a number of
15 different documents around CVS' collaboration with
16 Perdue, around the adherence program, CVS' collaboration
17 with other pro opioid lobbying organizations. I am not
18 specifically remembering that one document.

19 Q. I want to focus on that document if you don't
20 remember it, and maybe we should just move on, but I
21 would suggest to you that document doesn't say anything
22 about opioids. It is a document that is generic. You
23 don't have any --

24 THE COURT: That isn't productive, your
25 characterization or conclusion.

1 MR. BUSH: All right. Well, then, I will
2 pull it up, your Honor.

3 Can I do a sharer screen?

4 THE COURT: All right. We have only got a
5 couple more minutes.

6 THE WITNESS: Can you tell me where in my
7 report I cite the documents, so I can go to my report?

8 MR. BUSH: Tell you what. Let's just move
9 on. As I said, I didn't want to really get into
10 Defendant specific material.

11 It just struck me that that one was, in
12 particular, an interesting use of the document. We will
13 move on.

14 Let me see if I have anything else, your
15 Honor.

16 THE COURT: Okay.

17 (Pause.)

18 MR. BUSH: That's all. I am done. Thank
19 you, Dr. Lembke. I appreciate your time.

20 THE COURT: Okay. Thank you, Mr. Bush.
21 Mr. Weinberger, anything you want to ask?

22 MR. WEINBERGER: Yes, your Honor, just a few
23 questions.

24 - - - - -

25

1 EXAMINATION BY COUNSEL ON BEHALF OF THE PLAINTIFFS

2 BY MR. WEINBERGER:

3 Q. Dr. Lembke, at page 112 of your report, you discuss
4 the meeting convened by the National Association of Chain
5 Drug Stores in January of 2013, which was entitled "DEA
6 compliance working group." Do you recall that?

7 A. Yes.

8 MR. BUSH: I'm sorry. What was the page
9 number? I didn't hear it.

10 MR. WEINBERGER: Page 112.

11 MR. BUSH: Thank you.

12 BY MR. WEINBERGER:

13 Q. In that report, you indicate that the working group
14 included Walgreens representative as co-chair and
15 representatives of CVS, Rite Aid, and Wal-Mart as
16 participants. Do you recall that?

17 A. Yes.

18 Q. There is an exhibit in this case, which you've
19 referenced, which is a chart created for that working
20 group or by that working group of red flags. Do you see
21 it? Do you recall that?

22 A. Yes. And I believe I did mention that in my
23 testimony today.

24 Q. And those red flags are contained -- contain
25 annotations to various DEA enforcement actions and other

1 sources. Is that true?

2 A. Yes.

3 Q. And it is broken down as you did by categories,
4 patient conduct, physician conduct, and pharmacy conduct,
5 correct?

6 A. Yes.

7 Q. And the annotations include DEA enforcement actions
8 published in the Federal Register that go back as far as
9 the late '90s. Is that correct?

10 A. Yes.

11 Q. And you reference some of those cases including
12 the --

13 A. East Main Street document.

14 Q. Correct. That is dated back to 2010, correct?

15 A. Yes. Actually, I think the East Main Street is
16 2005-2006.

17 Q. You might be correct there.

18 Now, with respect to your testimony about
19 the Ohio PDMP-OARRS -- and you couldn't recall the date
20 that would be applicable to that PDMP as relates to the
21 pharmacies' conduct -- if I could refresh your memory,
22 although OARRS went into effect in 2006 in Ohio, in 2011,
23 there was a regulation that required review of the
24 OARRS-PDMP under certain circumstances by all
25 pharmacists. Is that correct?

1 A. Yes. That was in 2011.

2 Q. Okay. When you check the PDMP at your Clinic,
3 do you document your review of the PDMP and what was
4 found?

5 A. Yes.

6 Q. The pharmacies are in the process in this case of
7 producing their notes electronically as well as hard copy
8 of notes pursuant to Court order for our review to
9 determine what, if any, documentation was undertaken with
10 respect to red flags and specifically with respect to
11 checking the PDMP.

12 You have not had an opportunity to review
13 those documents as of yet, correct?

14 A. No. But that would be tremendously useful.

15 Q. Okay. We are working on a deadline right now, but
16 we will see what happens with that.

17 MR. WEINBERGER: Thank you, Dr. Lembke.
18 Judge Polster, that's all I have.

19 THE COURT: All right. Thank you,
20 Mr. Weinberger. All right.

21 I think we are concluded.

22 So Dr. Lembke, I appreciate it and again,
23 thank you for taking the time away from your clinical
24 practice and research and, candidly, your sleep because
25 it is pretty darn early, although my guess is you start

1 your professional day early as we all do. Thank you.

2 This has been very helpful to me, to have
3 this colloquy to better understand what you've done and
4 the basis for your conclusions, so I can address the
5 legal issues I need to.

6 So with that, we are adjourned and stay safe
7 everyone, and I know we have a phone call in about 10 or
8 12 minutes calling in. So thank you very much. We are
9 adjourned.

10 (Hearing concluded at 11:20 a.m.)

11 - - - - -

12
13 C E R T I F I C A T E

14 I, George J. Staiduhar, Official Court
15 Reporter in and for the United States District Court,
16 for the Northern District of Ohio, Eastern Division,
17 do hereby certify that the foregoing is a true
18 and correct transcript of the proceedings herein.

19
20
21
22 s/George J. Staiduhar
23 George J. Staiduhar,
Official Court Reporter

24 U.S. District Court
25 801 W. Superior Ave., Suite 7-184
Cleveland, Ohio 44113
(216) 357-7128